Periodic Adverse Drug Experience Report (PADER) (for drugs) or a Periodic Adverse Experience Report (PAER) (for biologics) (21 CFR 314.80(c)(2) and 600.80(c)(2), respectively). FDA has routinely granted waivers under 21 CFR 314.90(b) and 600.90(b) permitting applicants to submit an internationally harmonized Periodic Safety Update Report (PSUR) prepared in accordance with ICH E2C (see 62 FR 27470 (May 19, 1997) and 69 FR 5551 (Feb. 5, 2004)) instead of a PADER/PAER under conditions stated in the waiver. On November 15, 2012, the ICH Steering Committee signed off on the ICH harmonized guideline ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' and recommended that the PBRER format be adopted by the ICH regulatory bodies of the three regions. Therefore, the new and more comprehensive report format, the PBRER, has superseded the PSUR report format.

This guidance provides information on the steps applicants can take to submit a PBRER to the FDA in place of a PSUR, PADER, or PAER. The guidance discusses: (1) Applicants who have a waiver in place for their approved product to submit a PSUR instead of a PADER/PAER and (2) applicants who have not obtained a waiver and are currently submitting PADERs/PAERs as required under FDA regulations. Because the PBRER has replaced the PSUR as the ICH E2C harmonized postmarket safety report format, FDA is permitting applicants with an existing PSUR waiver to substitute the PBRER for the PSUR without submitting a new waiver request. This guidance describes the steps an applicant should take to submit the PBRER in place of the PSUR. For applicants who do not have a PSUR waiver in place for their approved application but would like to submit the PBRER in place of the PADER/PAER, this guidance provides information on how to submit a waiver request if they wish to do so.

This guidance describes the content, format, and submission deadlines applicants should follow when submitting the PBRER, as well as U.S.-specific appendices that should be submitted with the PBRER. It also explains how applicants can fulfill FDA's annual reporting requirement while submitting a harmonized PBRER that covers a longer reporting interval. In addition, the guidance notifies applicants that they may submit requests to be waived of the quarterly reporting requirement and instead, to submit PBRERs on a 6-month basis.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on providing postmarket periodic safety reports in the ICH E2C(R2) PBRER format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. The Paperwork Reduction Act of 1995

This draft guidance addresses information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information related to submission of waiver requests under §§ 314.90(a) and 600.90 have been approved under OMB control numbers 0910–0001 and 0910–0308. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08014 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 30, 2013, from 8:30 a.m. to 5:30 p.m.

Location: 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373.

Contact Person: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 5), email: *TPSAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: Modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from

FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a). Any person may submit an application seeking an order under section 911(g) of the FD&C Act.

Section 911(f) of the FD&C Act (21 U.S.C. 387k(f)) requires FDA to refer modified risk tobacco product applications to the Tobacco Products Scientific Advisory Committee (TPSAC) for its recommendations. TPSAC is required to report its recommendations on an application to FDA no later than 60 days after the date the application is referred to them. 21 U.S.C. 387k(f)(2). On April 30, 2013, FDA will present information to the committee on the process it will use to refer individual modified risk tobacco product applications to TPSAC.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: On April 30, 2013, from 8:30 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 23, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on April 30, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 15, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2013.

Closed Committee Deliberations: On April 30, 2013 from 3:30 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08069 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0329]

Center for Devices and Radiological Health: Health of Women Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop: ''The Center for Devices and Radiological Health (CDRH) Health of Women (HoW) Program: Educate, Enable, Enlist and Explore—HoW to Improve the Health of Women.'' CDRH is developing the HoW Program to explore unique issues in the regulation of medical devices related to the health of women and seeks public input on the priority activities. The CDRH HoW program seeks to bring together industry, clinicians, researchers, academia, government agencies, and patient/advocacy groups in an effort to: (1) Highlight device-specific clinical Study recruitment and retention strategies; (2) improve analysis and communication of sex-specific findings to providers and patients; (3) develop a priority research road map for the HoW device ecosystem. The workshop focus will be device- and disease-specific, patient centered, and action oriented.

Dates and Times: The public workshop will be held on June 24, 2013, from 8 a.m. to 5 p.m. and June 25, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held on FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993.

Contact: Nada Hanafi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993–0002, 301–796–5427, *Nada.Hanafi@fda.hhs.gov;* or Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5568, Silver Spring, MD 20993–0002, 301–796–6349, *Kathryn.OCallaghan@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on June 14, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration will be provided beginning at 7:30 a.m. on the day of the public workshop.

If you need special accommodations due to a disability, please contact Joyce Raines (*Joyce.Raines@fda.hhs.gov* or 301–796–5709) by 5 p.m. on June 14, 2013.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* and select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number and primary HoW Program area of expertise or interest. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the public workshop: The plenary portions of this